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10 **UNITED STATES DISTRICT COURT**
11 **EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND
DRUG ADMINISTRATION, et al.,

16 Defendants.

NO. 1:23-cv-03026-TOR

ORDER GRANTING PLAINTIFF
STATES' MOTION FOR
SUMMARY JUDGMENT

[PROPOSED]

17 This action involves a challenge under the Administrative Procedure Act
18 (APA) to the January 3, 2023, final agency action of Defendant U.S. Food and
19 Drug Administration (FDA) to subject mifepristone—a medication used by more
20 than 5.6 million patients in the United States over the last quarter century for
21 abortion and miscarriage management—to a Risk Evaluation and Mitigation
22 Strategy (REMS) with three Elements to Assure Safe Use (ETASU). This matter

1 came before the Court on Plaintiff States’ Motion for Summary Judgment and
2 Defendants’ Cross-Motion for Summary Judgment. The Court has considered the
3 following:

4 1. Plaintiff States’ Motion for Summary Judgment (ECF No. ____),
5 with supporting exhibits;

6 2. Defendants’ Combined Cross-Motion for Summary Judgment and
7 Opposition to Plaintiff States’ Motion for Summary Judgment (ECF No. ____),
8 with supporting exhibits;

9 3. Plaintiff States’ Combined Reply in Support of Motion for Summary
10 Judgment and Opposition to Defendants’ Motion for Summary Judgment
11 (ECF No. ____), with supporting exhibits;

12 4. Defendants’ Reply in Support of Motion for Summary Judgment,
13 with supporting exhibits; and

14 5. The administrative record in the above-captioned matter, including
15 the excerpts of the administrative record cited by the parties.

16 Being fully apprised of the matter, now, therefore, it is hereby

17 ORDERED, ADJUDGED, AND DECREED that the Plaintiff States’
18 Motion for Summary Judgment is hereby GRANTED and the Defendants’
19 Cross-Motion for Summary Judgment is DENIED.

20 The Court holds that the mifepristone REMS program violates the APA, as
21 FDA’s January 3, 2023, final agency action was “in excess of statutory jurisdiction,
22

1 authority, or limitations” and was “arbitrary” and “capricious,” 5 U.S.C.
2 §§ 706(2)(A), (C); and

3 REMANDS the matter to FDA with the following instructions to allow FDA
4 to address its errors without the potentially disruptive consequences of vacatur.
5 Accordingly, absent further order of the Court, the current mifepristone REMS
6 program adopted on January 3, 2023, shall remain in effect for the duration of the
7 remand. On remand, FDA shall consider the following: whether mifepristone
8 meets the statutory criteria to qualify for a REMS with ETASU based on the criteria
9 set forth under 21 U.S.C. §§ 355-1(a)(1), (f)(1)-(2), and (g)(4)(B), including
10 whether FDA would withdraw mifepristone from the market in the absence of any
11 ETASU; whether the ETASU elements are “commensurate with” mifepristone’s
12 well-established safety profile, *id.* § 355-1(f)(2)(A), particularly in comparison to
13 other comparable drugs and treatments; the extent to which the current (or any)
14 ETASU elements burden patient access to mifepristone, particularly given the
15 time-sensitive nature and risks of pregnancy, and also considering “patients who
16 have difficulty accessing health care,” including “patients in rural or medically
17 underserved areas,” *id.* § 355-1(f)(2)(C); and whether the current (or any) ETASU
18 for mifepristone “minimize[s] the burden on the health care delivery system,”
19 *id.* § 355-1(f)(2)(D). FDA is further ordered to consider those portions of the
20 administrative record that relate to the above statutory factors that it arbitrarily and
21 capriciously excluded from its 2023 REMS Review; and
22

1 ORDERS that the terms of the Court's prior Order Granting in Part
2 Plaintiffs' Motion for Preliminary Injunction, ECF No. 80, remain in effect during
3 the pendency of remand; and

4 DIRECTS that periodic reports shall be filed with the Court by FDA every
5 30 days as to the status of the mifepristone REMS review and the anticipated
6 timeframe for completion.

7 It is SO ORDERED.

8 ISSUED this _____ day of _____ 2025.

9
10 _____
JUDGE THOMAS O. RICE

11 Presented by:

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CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 10th day of October 2024, at Seattle, Washington.

s/ Kristin Beneski

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